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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,753	04/21/2004	Jeremy Clark	43496	5481

23552 7590 09/05/2006

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/828,753

Applicant(s)

CLARK, JEREMY

Examiner

Traviss C. McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-129 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6-8, 12-19, 21-23, and 27-30, drawn to compounds of claim 1 where the base is a purine, and compositions comprising the same, classified in class 514, subclass 45.
- II. Claims 1-11 and 16-26, drawn to compounds of claim 1 where the base is a pyrimidine, and compositions comprising the same, classified in class 514, subclass 49.
- III. Claims 2-4, 7-8, 18-19,, and 21-23, drawn to compounds of claim 1 where the base is a pyrrolopyrimidine (where Y is CH), and compositions comprising the same, classified in class 514, subclass 43.
- IV. Claims 31-34, 36-38, 42-45, and 107-109, drawn to methods of treating or preventing HCV using the compounds of group I, classified in class 514, subclass 45.
- V. Claims 31-41 and 107, drawn to methods of treating or preventing HCV using the compounds of group II, classified in class 514, subclass 49.
- VI. Claims 32-34 and 36-38, drawn to methods of treating or preventing HCV using the compounds of group III, classified in class 514, subclass 43.

Art Unit: 1623

- VII. Claims 46-49, 51-53, 57-60, 110, and 112-113, drawn to methods of treating or preventing a rhinovirus infection using the compounds of group I, classified in class 514, subclass 45.
- VIII. Claims 46-56 and 11, drawn to methods of treating or preventing a rhinovirus infection using the compounds of group II, classified in class 514, subclass 49.
- IX. Claims 47-49 and 52-53, drawn to methods of treating or preventing a rhinovirus infection using the compounds of group III, classified in class 514, subclass 43.
- X. Claims 61-64, 66-68, 72-75, 114, and 116-117, drawn to methods of treating or preventing yellow fever virus using the compounds of group I, classified in class 514, subclass 45.
- XI. Claims 61-71 and 114-115, drawn to methods of treating or preventing yellow fever virus using the compounds of group II, classified in class 514, subclass 49.
- XII. Claims 62-64 and 67-68, drawn to methods of treating or preventing yellow fever virus using the compounds of group III, classified in class 514, subclass 43.
- XIII. Claims 76-79, 81-83, 87-90, 118, and 120-121, drawn to methods of treating or preventing west Nile virus using the compounds of group I, classified in class 514, subclass 45.
- XIV. Claims 76-86 and 118-119, drawn to methods of treating or preventing west Nile virus using the compounds of group II, classified in class 514, subclass 49.
- XV. Claims 77-78 and 82-83, drawn to methods of treating or preventing west Nile virus using the compounds of group III, classified in class 514, subclass 43.

Art Unit: 1623

- XVI. Claims 91-94, 96-98, 102-105, 122, and 124-125, drawn to methods of treating or preventing a dengue virus infection using the compounds of group I, classified in class 514, subclass 45.
- XVII. Claims 91-101 and 122-123, drawn to methods of treating or preventing a dengue virus infection using the compounds of group II, classified in class 514, subclass 49.
- XVIII. Claims 92-94 and 97-98, drawn to methods of treating or preventing a dengue virus infection using the compounds of group III, classified in class 514, subclass 43.
- XIX. Claims 126 and 128, drawn to methods of making the claimed compounds using intermediate compound 1-4, classified in class 536, subclass 22.1.
- XX. Claims 127 and 129, drawn to methods of making the claimed compounds using intermediate compound 2-5, classified in class 536, subclass 22.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the bases attached to the sugars are distinct, as purines, pyrimidines, and pyrrolopyrimidines are known to be chemically divergent in structure and function. Chemical structures that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for

Art Unit: 1623

similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), and *In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure. As set forth supra, the structures of groups I-III are divergent as purines, pyrimidines, and pyrrolopyrimidines are known to be diverse in structure, and a search for one group would not be required for the other groups and a reference rendering one group obvious would not necessarily render the other groups obvious.

Inventions I-III and IV-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the products can be practiced with another materially different product, such as with the product of groups I-III, and the product as claimed can be practiced in a materially different process, such as in the processes of groups IV-XVIII.

Inventions I-III and XIX-XX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as

Art Unit: 1623

claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by either of the methods of group XIX or XX.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Claims 1-129 are generic to the following disclosed patentably distinct species: the plethora of divergent compounds represented by the compounds of groups I-III. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group represents, or 4) by naming a claim or an example which itself sets forth a single compound.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Due to the complexity of the instant restriction requirement, no telephone call was made to applicants to request an oral election to the above restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

Art Unit: 1623

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III
Art Unit 1623
August 23, 2006

